IN THE UNITED STATES DISTICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
FLORENCE DIVISION

Genesis Health Care Inc., Plaintiff, vs. Xavier Becerra *et al.*, Defendants.	Civil Action Number: 4:19-cv-01531-RBH

DEFENDANTS' COMBINED OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND CROSS-MOTION FOR SUMMARY JUDGMENT

Pursuant to the Court's May 28, 2023 Order (ECF No. 99), Defendants submit this opposition to Plaintiff's June 16, 2023 Motion for Summary Judgment (ECF No. 100, 100-1), and cross-move for summary judgment in Defendants' favor. For the reasons described in the accompanying brief, Plaintiff is not entitled to any of the declaratory relief it requests, and Defendants are entitled to summary judgment.

Respectfully submitted,

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July 28, 2023

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COMBINED BRIEF IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

This case centers on the Health Resource and Services Administration's ("HRSA") interpretation of the 340B statute, 42 U.S.C. § 256b. The statute establishes a discount-drug purchasing program ("340B Program") that is a critical part of the nation's healthcare safety net, offering under-resourced healthcare providers ("covered entities") the ability to purchase covered outpatient drugs at steep discounts so they can better serve their patients. Sometimes, the covered entities may bill insurers for reimbursement above the cost of acquisition, which allows them to generate revenue. However, the statute imposes a commonsense limitation known as the prohibition on diversion: a covered entity cannot "resell or otherwise transfer" 340B drugs "to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B). Moreover, the statute tasks HRSA with auditing covered entities' compliance with this prohibition, section 256b(a)(5)(C); imposing sanctions for non-compliance, sections (a)(5)(D), (d)(2)(B)(v); and resolving claims by manufacturers that a covered entity has violated the prohibition, sections (d)(3)(A), (B). The statute "balance[s]" complex and often "competing interests" nationwide, and HRSA must "use its expertise" to administer it. *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 119-20 & n.6 (2011).

Plaintiff Genesis Health Care, Inc. ("Genesis") participates in the 340B Program. It set up a practice where it would provide 340B drugs that it bought at a discount not only to its patients, but also to other individuals who had only an attenuated connection to Genesis. Genesis, in turn, would get reimbursement for the drugs, allowing it to significantly profit from these transactions. When HRSA discovered this practice as a result of a 2017 audit, it sought to bring Genesis into compliance with its statutory obligations as a 340B covered entity. Genesis sued.

As the Fourth Circuit explained, this case was "filed fundamentally to challenge HRSA's final audit report" under the Administrative Procedure Act ("APA"). *Genesis Healthcare, Inc. v. Becerra*, 39 F.4th 253, 260, 262 (4th Cir. 2022). Genesis "alleged that to comply with" the standards applied in HRSA's audit; Genesis would have to change its business practices. *Id.* at 261. Even though HRSA fully voided its audit determination, the Fourth Circuit determined that the case is not moot. *Id.* at 259. HRSA continues to stand by its interpretation of the prohibition on diversion. *Id.* at 260-61.

Now, Genesis moves for summary judgment granting it declaratory relief. While Genesis's motion is unfocused and pervasively ambiguous—and wholly fails to identify a cause of action—Defendants explain why, consistent with the Fourth Circuit's decision, this action must be understood as an APA challenge to HRSA's audit determination. Once Genesis's challenge is brought into proper focus, it is clear that its APA claim fails for two reasons. First, Genesis has waived its statutory interpretation argument. Second, the APA's prejudicial-error requirement forecloses relief.

As for the requested declaratory relief, the proposed declarations are frustratingly ambiguous and inherently circular because they use the phrase "patient of a covered entity" when the crux of the dispute is how to interpret such language. As best as Defendants can understand the proposed declarations, they mostly set forth propositions that HRSA does not dispute; therefore, declaratory relief would be unnecessary and improper. But there is one key dispute: Genesis is wrong that section 256b(a)(5)(B) "requires that any prescription from any source is available to a patient of a covered entity." Pl. MSJ[1] at 20. Allowing Genesis to provide 340B

[1] Citations to "Pl. MSJ" refer to Plaintiff's June 16, 2023 Memorandum in Support of Motion for Summary Judgment, ECF No. 100-1.

discount drugs to any individual regardless of whether the individual is a "patient of" Genesis—i.e., the individual received the drugs as part of Genesis's medical care for the individual—contravenes the text, structure, and purpose of the 340B statute.

For all these reasons, Defendants are entitled to summary judgment.

BACKGROUND

I. Statutory Framework

Section 340B of the Public Health Service Act, codified at 42 U.S.C. § 256b, establishes a program (the "340B Program") whereby drug manufacturers enter into agreements with the Secretary of the Department of Health and Human Services ("HHS") to provide discounts on certain drugs ("covered outpatient drugs") to certain statutorily delineated healthcare providers ("covered entities"). The Program is administered by the Health Resources and Services Administration ("HRSA"), a component of HHS, pursuant to authority delegated by the Secretary.

Section 256b(a)(4) defines the "covered entities" eligible to participate in the Program. It includes federally-qualified health centers ("FQHCs"), AIDS drug purchasing assistance programs, black lung clinics, disproportionate share hospitals, and others. Since its inception in 1992, the 340B Program has proven to be a critical tool for covered entities to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services," H.R. Rep. 102-384(II) (Sept. 22, 1992) (emphasis added), by allowing covered entities to purchase drugs at a reduced price—sometimes for as little as a penny. *See* 42 C.F.R. § 10.11(b). Over 13,000 covered entities participate. *See* 87 Fed. Reg. 73,516, 73,524 (Nov. 30, 2022).

Section 256b(a)(5) imposes "requirements for covered entities." Section 256b(a)(5)(B), titled "Prohibiting the resale of drugs," says "With respect to any covered outpatient drug that is

subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity." This is often called the prohibition on diversion. And section 256b(a)(5)(C), titled "Auditing," says "A covered entity shall permit the Secretary … to audit ... the records of the entity that directly pertain to the entity's compliance with" the prohibition on diversion.

The primary stakeholders in the 340B Program are drug manufacturers, on the one hand, and covered entities, on the other. Their interests are often in tension: manufacturers must participate in the Program if they voluntarily participate in Medicaid and Medicare Part B to obtain reimbursement for their products, thus they naturally want to limit the volume of 340B discounts. And covered entities want the opposite. It is in this context that HRSA has sought to bring clarity to Program participants by issuing guidance on HRSA's interpretation of the statutory requirements and, accordingly, how HRSA will administer the Program.

In August 1995, HRSA issued a Federal Register notice that described its proposed approach to the statutory requirement that "a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity." 60 Fed. Reg. 39,762 (Aug. 3, 1995). The guidance was finalized in 1996. 61 Fed. Reg. 55,156 (Oct. 24, 1996). The guidance sought to "explain how the Department intends to administer the 340B program" by "clarifying the meaning given by the Department to particular words of phrases." *Id.* at 55,156. The guidance merely "explain[ed] the statutory language"—it was not meant to "create … new law [or] new rights or duties" and in HRSA's view it did not "exceed the purpose of 340B or conflict with any of its provisions." *Id.* Because the prohibition on diversion turns on who, exactly, is a "patient of the entity," this guidance became known as the "patient definition" or "patient-eligibility guidelines."

HRSA interpreted the statute to mean that, in essence, the covered entity had to be responsible for the medical care in question: the covered entity had to maintain records of the individual's care, and the care provider had to be employed by the covered entity or else receive a referral from the covered entity (under a contractual or other arrangement, like a referral for consultation) such that responsibility for the care provided remained with the covered entity. *See id.* at 55,157-58. As is inevitable in this context, commenters had different reactions to HRSA's interpretation of the phrase "patient of the entity." *See, e.g.*, A.R.[2] 44, 46, 48 (commenters expressing support); *id.* at 50 (arguing it is too narrow); *id.* at 55, 58, 74 (arguing it is too broad). Ultimately, HRSA's commonsense understanding of the statutory language sought to account for the multitude of different contexts and covered entities included in the Program, *see* 42 U.S.C. § 256b(a)(4) (comprising 15 subparagraphs delineating 22 different types of covered entities); 61 Fed. Reg. at 55,157, while outlining reasonable principles that would effectuate the statutory limitation on each covered entity to only use the Program for individuals who truly were "patient[s] of the entity." The 1996 guidance continues in effect to this day.[3]

II. The Genesis Audit

In 2017, HRSA's Bureau of Primary Health Care ("BPHC"), which administers a different HRSA program, received allegations from two of its health center grantees in South Carolina that Genesis was misusing the 340B Program. A.R. 9052. BPHC referred the matter to HRSA's Office of Pharmacy Affairs ("OPA"), which administers the 340B Program. According to the allegations,

[2] Citations to "A.R." refer to the certified administrative record submitted in this case.

[3] Defendants' discussion of prior guidance is curtailed because, as discussed *infra* 13-14, it appears that Genesis is only challenging language contained in the audit determination, not the guidance. While Genesis spends some time criticizing proposed guidance from 2015, *see* Pl. MSJ at 12-13, 16, Genesis admits that that guidance was withdrawn, *see id*. Genesis also points to language issued by HRSA's Bureau of Primary Healthcare, *see* Pl. MSJ at 9, 11, but that office does not administer the 340B Program and the language pertains to a different statutory authority.

Genesis was "enrolling specialty practices in [memoranda of agreement]," claiming that "if the specialty practices send patients to Genesis for primary care," the specialty practices—which themselves were not eligible for 340B participation—"would be eligible for 340B benefits" based on the arrangement with Genesis. *Id.* In response, HRSA conducted a targeted audit of Genesis on June 21-22, 2017.

In a February 14, 2018 audit report, the agency preliminarily determined that Genesis had failed to comply with several 340B Program requirements. A.R. 192-93. With respect to diversion, HRSA determined that Genesis's in-house pharmacy and several of its contract pharmacies had dispensed 340B drugs to individuals without sufficient documentation of a provider-patient relationship between Genesis and those individuals. In addition, Genesis's in-house pharmacy at 201 Cashua Road had used 340B drugs to fill prescriptions that were written by private physicians' practices that were not eligible as 340B covered entity sites. Genesis did not have patient records to support Genesis's responsibility for the care delivered by these private physician practices, nor was Genesis able to show that the individuals received healthcare services from a healthcare professional who was either employed by Genesis or under a contractual or other arrangement (such as referral for consultation) demonstrating Genesis's responsibility for the individuals' care. In addition, auditor working papers indicated that Genesis pharmacy technicians had added the note "medication referral" into individuals' visit history after filling prescriptions with no documented referral. A.R. 4412-14.

The audit also found that Genesis failed to maintain auditable records, independent of the diversion finding. A.R. 192. Due to this finding, HRSA notified Genesis that it would be removed from the 340B Program, and that Genesis would be responsible for repaying affected manufacturers the total amount of the improper discount passed on to ineligible individuals.

Genesis disputed the preliminary audit report in a March 13, 2018 letter (A.R. 206-221), arguing that the audit failed to take into consideration various Genesis policies and records. But Genesis's arguments did not address HRSA's concerns. For example, Genesis's written policy stated that its in-house pharmacy would dispense a 340B drug to an individual if Genesis maintained a medical record for that individual within the last two years, regardless of whether the prescription was related to the healthcare services provided at Genesis. A.R. 219. On June 26, 2018, HRSA affirmed its audit findings and terminated Genesis from the 340B Program. A.R. 1499-1503. It invited Genesis to submit a Corrective Action Plan addressing each adverse finding as a condition of re-enrolling in the 340B Program. A.R. 1502-03.

The record provides insight into Genesis's misuse of the 340B Program. A flowchart outlining Genesis's practices for "340B Eligibility" showed that as long as there was a "documented referral to or from provider," along with a documented diagnosis and progress notes, Genesis would fill an individual's prescription with 340B drugs. A.R. 9275 (emphasis added). That is, Genesis would allow a provider with no connection to Genesis to send prescriptions for fulfillment with 340B drugs at Genesis's pharmacy based merely on the existence of a past referral from that provider.

And even without a "documented referral to or from provider," the flowchart showed that Genesis would still provide 340B drugs to an individual as long as an "encounter" is created within the individual's electronic medical record, the medication is noted, progress notes are added, and a referral request is initiated. This approach permitted the prescription from outside providers to be filled with 340B drugs at the Genesis pharmacy without any type of referral, as long as supporting documentation is added to the individual's medical record.

Genesis also provided a policy-and-procedure document describing scenarios in which it considered an individual eligible to receive 340B drugs. A.R. 9305-08. One of the scenarios states:

> Individual has been seeing specialist B long before the individual started seeing [Genesis's] physician A. Specialist B did not refer the individual to [Genesis]. Individual wants to continue to see specialist B and physician A. The individual fills the prescription from specialist B at [Genesis's] pharmacy. The individual is 340B eligible (if the scope of the service provided is consistent with the scope of the services indicated on [Genesis's Health Center Program forms for in-scope services], and [Genesis] maintains responsibility for the patient's care) to fill the prescription at Genesis's in-house pharmacy/contract pharmacies.

A.R. 9307. In other words, Genesis believed it could treat an individual as a Genesis 340B-eligible patient for all of the individual's prescription purposes, even when those prescriptions were written by providers who had no connection to Genesis.

A separate policy-and-procedure document entitled "Outside Referral Medication" also described Genesis's 340B dispensing practices. A.R. 9270-71. When "[a] prescription is received, via hard copy or electronically, into a GHC [Genesis Health Care] pharmacy from an outside referral source," Genesis's case management department determines if there is a "Provider Partnership Agreement with the prescribing provider or entity" in order to fill the prescription with 340B drugs. The "Provider Partnership Agreement" is defined as "a verbal or written agreement between a prescribing outside provider and GHC, where GHC enters into an agreement to oversee and manage the patient's care in coordination with the prescribing provider." But the agreement itself raises doubt that Genesis would actually be overseeing the individual's care instead of merely filling the outside provider's prescription orders: it appears that the referral provider maintained its own treatment records that were only shared with Genesis upon request. *See* A.R. 9273.

The problems were underscored by specific episodes from the universe of 340B transactions that the auditor sampled. For example, Genesis provided medical records for an individual who was seen at Genesis for a knee-related issue in April 2014, an annual gynecological

exam in April 2015, and an order for a gynecologic pap test in July 2017. A.R. 1173-78. However, the prescription in question (which was filled with 340B drugs) was for high blood pressure medication and was written by the patient's primary care provider in September 2016. A.R. 194, 1508. The patient's primary care provider was listed in Genesis's medical record as an outside provider, and Genesis did not provide any documents supporting a contractual or other arrangement with the outside provider. *Id.*; A.R. 1180. Nevertheless, Genesis used 340B drugs to fill the prescription from this outside provider based on Genesis's policy of using a two-year lookback window to determine if a patient had any visits with a Genesis provider, regardless of whether the previous visits with Genesis providers were related to the specific condition associated with prescriptions written by the outside providers. *See* A.R. 1488.

Similarly, Genesis provided medical records for an individual that included blood pressure readings at Genesis from September 2012 through October 2017, a September 2016 operative report for a surgical procedure at a non-Genesis facility, and a gynecological exam at Genesis in October of 2017. A.R. 1364-72. The prescription at issue was for acid reflux treatment and was written by the individual's primary care provider in February 2017. A.R. 195, 1509. The individual's primary care provider was listed in Genesis's medical record as an outside provider. A.R. 1375. Yet Genesis filled the prescription with 340B drugs because, as reflected in the records, the outside primary care provider referred the individual to Genesis (rather than Genesis referring the individual to an outside provider) for various services, including an annual gynecological exam. A.R. 1369-85.

III. Genesis Sues to Challenge HRSA's Audit Determination

Shortly after HRSA terminated Genesis from the 340B Program in June 2018, Genesis brought suit asking this Court to "review and set aside [HRSA's] wrongful determination to

remove Genesis from the" 340B Program. *See* Pet. (ECF No. 1) at 1. In September 2018, HRSA amended its audit determination to remove the sanction of disqualification, thus reinstating Genesis to the 340B Program, but otherwise maintained its findings of noncompliance. A.R. 1520-1524. The case was stayed while HRSA and Genesis developed a mutually agreeable Corrective Action Plan ("CAP") for Genesis. *See* ECF Nos. 11, 12, 17, 18, 20, 21, 23, 24, 27, 28.

HRSA approved Genesis's CAP by letter dated March 20, 2019. A.R. 1541. The letter stated, consistent with HRSA's position throughout the audit, that "in order for an individual to qualify as a 340B patient, [Genesis] must have initiated the healthcare service resulting in the prescription, regardless if the patient had an unrelated billable FQHC encounter." And it reiterated, consistent with HRSA's position throughout the audit, that Genesis could provide 340B prescriptions to patients referred to outside providers, but must demonstrate that responsibility for care remains with Genesis. Despite the months of negotiations resulting in an approved CAP, Genesis nevertheless filed an amended complaint alleging that the March 20, 2019 letter sought to "enforce a definition of 'patient' that contradicts the plain language of the statute and that has never been promulgated by regulation." ECF No. 33 at 2.

HRSA voided the audit findings in full by letter dated June 6, 2019. A.R. 1544. That included voiding the "September 24, 2018 letter [and] accompanying revised final audit report" and the "March 20, 2019 letter approving [Genesis's] corrective action plan." The letter further explained that because "the audit findings have been voided," Genesis "has no further obligations or responsibilities in regard to the audit," including no obligation to "perform the actions outlined in the CAP previously submitted to OPA."

This Court eventually dismissed Genesis's lawsuit as moot. *See* ECF No. 49. Genesis appealed, and the Fourth Circuit reversed. *Genesis*, 39 F.4th at 259-61. Now, the case is before the Court for disposition on cross-motions for summary judgment.

LEGAL STANDARD

In a case involving review of final agency action under the APA, summary judgment is not decided by the typical standards applicable under Federal Rule of Civil Procedure 56. *See, e.g.*, *J.O.C. Farms, LLC v. Rural Cmty. Ins. Agency, Inc.*, 131 F. Supp. 3d 514, 524 (E.D.N.C. 2015); *Pres. Soc'y of Charleston v. U.S. Army Corps of Eng'rs*, No. 2:12-cv-2942-RMG, 2013 WL 6488282, at *1 n.1 (D.S.C. Sept. 18, 2013). Instead, summary judgment is the vehicle by which a court decides, as a matter of law and based on the administrative record compiled by the agency, whether the challenged action is consistent with applicable APA standards. *See, e.g.*, *3V Sigma USA, Inc. v. Richardson*, No. 2:20-cv-807-DCN, 2021 WL 809399, at *3 (D.S.C. Mar. 3, 2021); *J.O.C. Farms*, 131 F. Supp. 3d at 524; *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744-45 (1985). "Moreover, under the APA, the plaintiff has the burden of proof and must demonstrate that defendants' actions were arbitrary, capricious, and abuse of discretion, or otherwise not in accordance with law." *J.O.C. Farms*, 131 F. Supp. 3d at 524 (citing *Sierra Club v. Marita*, 46 F.3d 606, 619 (7th Cir. 1995)).

A court's review of an agency's interpretation of a statute that it administers—here, HRSA's interpretation of the 340B statute—is "narrow" and "highly deferential." *Pres. Soc'y*, 2013 WL 6488282, at *1 (quoting *Marsh v. Or. Nat. Res.*, 490 U.S. 360, 378 (1989)). Agency action "will be set aside only" if "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law"; "[r]eview under this standard is highly deferential, with a presumption in favor of finding the agency action valid." *Deerfield Plantation Phase II-B Prop. Owners Ass'n,*

Inc v. U.S. Army Corps of Eng'rs, 801 F. Supp. 2d 446, 457 (D.S.C. 2011) (Harwell, J.) (quoting *Ohio Valley Envtl. Coal. v. Aracoma Coal Co.*, 556 F.3d 177, 192 (4th Cir. 2009)). "An agency's construction of a statute or regulation which it is charged with administering is generally entitled to deference by the courts and should be overturned only if plainly erroneous or inconsistent with the regulation." *Pres. Soc'y*, 2013 WL 6488282, at *1 (citing *Fed. Mar. Comm'n v. Seatrain Lines, Inc.*, 411 U.S. 726, 745-46 (1973); *Ohio Valley Envtl. Coal.*, 556 F.3d at 193 (citing *Auer v. Robbins*, 519 U.S. 452, 461 (1997))) (quotes omitted).

ARGUMENT

Genesis seeks summary judgment granting it four declarations[4] related to the statutory requirement that a covered entity shall not "resell or otherwise transfer" 340B drugs "to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B). Genesis's motion does not identify a cause of action, but as explained below, this lawsuit must proceed as a challenge under the APA to HRSA's audit determination. Once the claim is brought into proper focus, it becomes clear that Genesis's challenge fails under APA principles of waiver and harmless error.

In any event, Genesis is not entitled to any of the declarations it seeks. The core question here is what it means to be a "patient of the entity" under the statute. After all, if a person went to Hospital X's emergency room five years ago, is he a patient of Hospital X today? Or, if a person goes to Health Center Y for a flu vaccine, is she a patient of Health Center Y for obtaining cancer medications if treated by a cancer specialist unaffiliated with Health Center Y? As explained below, Genesis's proposed interpretation of (a)(5)(B) is inconsistent with the foundational principles of statutory interpretation and should be rejected.

[4] Genesis's cover motion and its brief contain a numbered list of six proposed declarations. Pl. MSJ at 20-21. Two of them are duplicative. *See id.* (four and five are the same as one and two).

Finally, if the Court is inclined to grant any portion of Genesis's motion, its judgment should make clear that the declaratory relief is limited to Genesis. Declaratory relief is party-specific, not universal. Genesis's proposed declarations, as they are currently worded, fail to account for this limit on declaratory relief.

I. APA Doctrines of Waiver and Harmless Error Bar Relief Here.

Genesis has moved for summary judgment without articulating any cause of action cognizable in federal court. As relevant here, a litigant that wants relief from a federal court pursuant to federal-question jurisdiction, 28 U.S.C. § 1331, has to identify a cause of action arising under federal law. *See, e.g.*, *Merrell Dow Pharma. Inc. v. Thompson*, 478 U.S. 804, 808 (1986). And if a litigant wants to sue the United States government, it has to identify a waiver of sovereign immunity. *See, e.g.*, *F.D.I.C. v. Meyer*, 510 U.S. 471, 475 (1994) ("Absent a waiver, sovereign immunity shields the Federal Government and its agencies from suit.").

Although Genesis invokes the APA in its amended complaint, ECF No. 33 at ¶ 6, Genesis does not explain in its motion what "agency action" it is challenging; whether that agency action is "final"; and whether or how that final agency action does or does not pass muster under 5 U.S.C. § 706(2). Of course, "[a] party waives an argument by failing to present it in its opening brief or failing to develop its argument." *Deloach v. Saul*, No. 0:20-cv-2150-PJG, 2021 WL 1940553, at *3 (D.S.C. May 14, 2021) (quoting *Grayson O Co. v. Agadir Int'l LLC*, 856 F.3d 307, 316 (4th Cir. 2017)) (cleaned up). Nevertheless, Defendants infer that Genesis is raising an APA challenge[5] to HRSA's audit determination, including HRSA's March 2019 CAP letter. Genesis opens its

[5] To the extent that Genesis intends to stand on its misguided theory that this is an "ordinary declaratory judgment action," *see* Pl. Proposed Scheduling Order (ECF No. 68-1) at 2, Defendants have previously explained why that makes no sense, *see* Defs. 26(f) Addendum (ECF No. 69) at 6-8. Nor can Genesis proceed directly under the 340B statute. *Astra USA*, 563 U.S. at 117 (there is no private right of action under the 340B statute).

motion, Pl. MSJ at 3, by quoting language from that letter. It then compares that language to section 256b(a)(5)(B) and argues that "HRSA's interpretation … adds an additional element that is not within the plain language of the statute." Pl. MSJ at 3. *See also id.* at 8. The Fourth Circuit also understood this action as one under the APA. *See Genesis*, 39 F.4th at 263.

Thus, if the Court is to infer an APA claim for Genesis, the proper focus of that claim is HRSA's audit determination, including the March 2019 letter. The Court need not opine on HRSA's 1996 guidelines or any of the other documents cited in passing by Genesis.[6]

Having identified the appropriate APA framework for Genesis's motion, two problems become clear. First, Genesis waived its statutory interpretation claim by failing to raise it during the audit. Second, the APA's harmless-error rule forecloses relief. Defendants are entitled to summary judgment for both reasons.

A. Genesis has waived its statutory interpretation claim.

Section 706(2) of the APA sets forth the standards that this Court must use to evaluate agency action. Genesis does not offer any argument about how any agency action contravenes any of those standards. That means Genesis has waived the core argument necessary to support its request for relief. Nevertheless, the most plausible candidate for an APA claim would be that HRSA's audit determination interpreted the diversion prohibition, section 256b(a)(5)(B), in a manner that is "not in accordance with law." 5 U.S.C. § 706(2)(A). *See also Genesis*, 39 F.4th at 262 (APA allows for claim seeking "declaratory relief that a term relied on by the agency in its action has a different meaning than the one that the agency gave to it"). Yet, that claim fails because Genesis never raised its statutory interpretation argument during the audit itself.

[6] Moreover, any challenge to the 1996 guidelines themselves is time-barred. *See Jersey Heights Neighborhood Ass'n v. Glendening*, 174 F.3d 180, 186 (4th Cir. 1999).

Ample APA case law bars Genesis from advancing its argument for the first time in this Court. "It is beyond cavil that a petitioner's failure to assert an argument before an administrative agency bars it from asserting that argument for the first time before a reviewing court." *Alzokari v. Pompeo*, 394 F. Supp. 3d 250, 256 (E.D.N.Y. 2019), *rev'd on other grounds*, 973 F.3d 65 (2d Cir. 2020) (quoting *Ry. Labor Execs.' Ass'n v. United States*, 791 F.2d 994, 1000 (2d Cir. 1986)). *See also, e.g.*, *Hispanic Affairs Project v. Acosta*, 263 F. Supp. 3d 160, 186 (D.D.C. 2017), *rev'd on other grounds*, 901 F.3d 378 (D.C. Cir. 2018) ("As the D.C. Circuit has frequently reminded, issues not raised before an agency are waived and will not be considered by a court on review.") (quotes omitted, citing cases); *United States v. L.A. Tucker Truck Lines, Inc.*, 344 U.S. 33, 37 (1952) ("[C]ourts should not topple over administrative decisions unless the administrative body … has erred against objection made at the time appropriate under its practice.").

Throughout the audit proceedings and its extensive communications with HRSA, *see* A.R. 206-39, 9070-76, 9078, 9104-07, 9140-48, 9153-66, 9178-80, 9219-77, 9280-327, Genesis disputed the audit findings by asserting that it had in fact complied with HRSA's interpretation of (a)(5)(B) and that there were procedural flaws in the audit. But Genesis did not make the statutory interpretation argument it now advances: that HRSA has misinterpreted the phrase "patient of the entity" in (a)(5)(B) by imposing an extra-statutory restriction about the origin of the prescription. Indeed, that argument was not even part of the initial complaint in this action. *See* ECF No. 1. Thus, the Court should grant summary judgment to Defendants because under APA principles Genesis has waived its challenge to HRSA's interpretation of the statute.

B. The APA's harmless error rule bars relief.

The APA instructs that courts reviewing agency action must take "due account" "of the rule of prejudicial error." 5 U.S.C. § 706. Thus, "[i]n administrative law, as in federal civil and

criminal litigation, there is a harmless error rule." *Nat'l Ass'n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 659-60 (2007) (quoting *PDK Labs. Inc. v. D.E.A.*, 362 F.3d 786, 799 (D.C. Cir. 2004)). If the agency's alleged error—here, HRSA's alleged misinterpretation of (a)(5)(B)—"did not affect the outcome," *PDK Labs.*, 362 F.3d at 799, then this Court should not grant relief under the APA. *See also Avail Vapor, LLC v. F.D.A.*, 55 F.4th 409, 425-26 (4th Cir. 2022).

Here, HRSA's determination of noncompliance and disqualification of Genesis was based on two separate grounds: one, that Genesis did not comply with the statutory prohibition on diversion; and two, that Genesis did not comply with the statutory requirement under section 256b(a)(5)(C) to maintain auditable records. *See* A.R. 1499-1503, 1520-24, 1541-43. Genesis wholly ignores this second finding in its motion. So even if HRSA were wrong about the scope of the prohibition on diversion, Genesis fails to explain how it could have avoided a finding of noncompliance and disqualification from the 340B Program based on the independent finding that it failed to maintain auditable records. Moreover, the entire audit determination has been voided. For these reasons, the APA's harmless-error rule bars relief here.

II. Defendants are Entitled to Summary Judgment with Respect to Each Declaration that Genesis Seeks.

Even if the Court reaches the merits, Defendants are entitled to summary judgment. HRSA has properly interpreted the statutory phrase "patient of the entity." And the other declaratory relief that Genesis seeks is irrelevant or unnecessary. At the least, given the lack of clarity in the proposed declarations, the Court should allow Defendants to propose a more precisely worded judgment for the Court's consideration if the Court is inclined to rule for Genesis.

A. HRSA has properly interpreted the statutory phrase "patient of the entity."

HRSA interprets the phrase "patient of the entity" in section 256b(a)(5)(B) to mean that the covered entity "initiated the healthcare service resulting in the prescription." A.R. 1541.

Genesis contends that HRSA's interpretation "improperly embellishes" the statute by "excluding [individuals] who have an unrelated encounter" with Genesis. Pl. MSJ at 8. HRSA's reading of (a)(5)(B) is correct; Genesis, on the other hand, offers an overly expansive standard that would not constitute a workable interpretation of the statute.

To start, HRSA's interpretation of the 340B statute in its audit determination is entitled to deference under *United States v. Mead Corp.*, 533 U.S. 218 (2001), and the deferential APA standards articulated above, *supra* 11.[7] Even without the authority to make rules carrying the force of law, 533 U.S. at 226, an agency's statutory interpretation "merit[s] some deference whatever its form, given the specialized experience and broader investigations and information available to the agency and given the value of uniformity in its administrative and judicial understandings of what a national law requires," *id.* at 234 (quotes omitted).

Regardless of the deference owed HRSA, its interpretation should prevail. The key question here is how to read the phrase "patient of the entity" in the 340B statute. To answer that question, courts employ various grammatical and structural canons of statutory interpretation to ensure that a statutory scheme is coherent and consistent. *Healthkeepers, Inc. v. Richmond Ambulance Auth.*, 642 F.3d 466, 471-72 (4th Cir. 2011); *see also Bank of Am. Corp. v. United States*, 2023 WL 1997806, at *5 (W.D.N.C. Feb. 14, 2023) ("Under the grammar canon of statutory interpretation, words are to be given the meaning that proper grammar and usage would assign them.") (quotes and alterations omitted). In (a)(5)(B), the prepositional phrase "of the entity" modifies the noun "patient" and connotes in its ordinary grammatical meaning a possessive relationship between the patient and the entity. *See* The Chicago Manual of Style Online, 5.172

[7] Defendants do not assert that the audit determination is entitled to *Chevron* deference. That renders much of Genesis's argument, *see* Pl. MSJ at 14, irrelevant.

(defining "preposition" as "an uninflected function word or phrase linking a noun element (the preposition's object) with another part of the sentence to show the relationship between them"); *id.* 5.172, 5.177 (the preposition "of" expresses the notion of "source" or "possession"). Put simply, "patient of the entity" can be reduced to its possessive form, the "entity's patient." Genesis itself acknowledges as much. *See* Pl. MSJ at 3 ("By this plain language, Genesis may fill prescriptions for any person who is a Genesis patient.").

What does it mean to be Genesis's patient? It is this very connection that HRSA sought to elucidate when it told Genesis that it "must have initiated the healthcare service resulting in the prescription" for a person to be a Genesis patient under the statute and thus eligible to receive a 340B drug. This statement, along with others from HRSA to Genesis about what it means to be a Genesis patient for purposes of 340B Program compliance (i.e., that Genesis employed or was under contract with the professional that rendered the healthcare service, and that Genesis demonstrated that care for the person remained with Genesis, *see* A.R. 1541) is a reasonable and commonsense way of giving effect to Congress's words and the legislative intent to link the "patient" with "the entity." Genesis, on the other hand, thinks it should be permitted to purchase discounted blood-pressure medication for an individual seeing a non-Genesis provider when the individual's only connection to Genesis is a gynecological exam. *See supra* 8-9.

Notably, (a)(5)(B) uses the present tense. *See Carr v. United States*, 560 U.S. 438, 447-48 (2010) ("Congress' use of a verb tense is significant in construing statutes[.]"). It prohibits covered entities from transferring 340B drugs to "a person who <u>is not</u> a patient of the entity" (emphasis added), as opposed to "a person who [has never been] a patient of the entity," which indicates a requirement that there be an ongoing relationship between the entity and the person. HRSA's interpretation gives meaning to "is" because connecting the prescription for the drugs dispensed

to the covered entity itself helps ensure a present relationship. *See also* 61 Fed. Reg. at 55,157 (noting that state laws concerning prescription refills would help address commenter's concern that an individual could "obtain one medical treatment from a covered entity at any time in his or her lifetime then continue (forever) to purchase drugs"). On the other hand, Genesis's proposed approach of filling an individual's prescriptions with 340B drugs based on an individual's "unrelated encounter" with Genesis at some unspecified point in the past, *see* Pl. MSJ at 8, provides no assurance that the individual "is" a patient of Genesis.

HRSA's baseline interpretation of the statute, including its view that a covered entity should use 340B-discount drugs for prescriptions that are actually part of the covered entity's care for an individual, is not stringent. Genesis incorrectly attempts to portray HRSA's interpretation as a "narrow restriction" that "embellishes" the statute, Pl. MSJ at 8, 18, but in truth, HRSA's interpretation sets forth only minimal requirements that help ensure that a covered entity has more than a remote or tangential connection to a person before it purchases 340B drugs for that person. In that way, HRSA's reading is completely consistent with the statutory text that links the patient with the covered entity, and at the very least, the Court can defer to HRSA's view. Genesis, on the other hand, would have this Court believe that "patient of the entity" means whatever any one of the 22 regulated entity types—including federally-qualified health centers, HIV/AIDS clinics, children's hospitals, rural hospitals, cancer hospitals, and safety-net hospitals—says it means, divorced from any ordinary, common understanding of the minimum contacts sufficient to establish a patient-provider relationship. Implicit in Genesis's reasoning is that for purposes of dispensing 340B drugs, a patient-provider relationship can spring forth even when only an attenuated connection exists between the person and the entity (and even though, as explained *infra* 25, it is doubtful that Genesis would accept responsibility for the person's care in terms of

liability for any adverse drug reactions). After all, Genesis was filling prescriptions written by individuals' primary care providers, unaffiliated with Genesis, based on record-keeping maneuvers to paper up purported "referrals." *See supra* 6-8.

Genesis is just one of the over 13,000 covered entities that participate in the 340B Program for which HRSA exercises programmatic oversight. HRSA has to devise a workable and commonsense mechanism to ensure that participating entities are complying with the statute's prohibition on diversion. Its construction only sets minimum guideposts for ascertaining when a person who is claimed to be a patient bears a sufficient connection or link to the entity that dispensed the drug so as not to run afoul of (a)(5)(B).

The language in (a)(5)(B) also has to be squared with the rest of the 340B statute. Interpreting statutes consistent with the ordinary meaning of the statutory text in order to effectuate Congress's intent does not mean that courts read the phrase "patient of the entity" in a "vacuum," *Gundy v. United States*, 139 S. Ct. 2116, 2126 (2019). To faithfully ascertain Congress's intent, the Court must read the "the words … in their context and with a view to their place in the overall statutory scheme." *F.D.A. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000); *accord Abramksi v. United States*, 573 U.S. 169, 179 (2014); *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291 (1988). Here, the statute directs the Secretary of HHS to (1) audit covered entities' compliance with the prohibition on diversion, § 256b(a)(5)(C); (2) impose sanctions for diversion, *id.* (a)(5)(D), (d)(2)(B)(v); and (3) establish a dispute resolution process to address claims of diversion, *id.* (d)(3)(A), (d)(3)(B)(i). Of note, the oversight and compliance provisions in section 256b(d) were part of a 2010 amendment that was specifically intended to strengthen HRSA's oversight of regulated entities, including covered entity compliance with the prohibition on diversion. *See* Pub. Law 111-148, § 7102 (entitled "Improvements to 340B Program Integrity");

see also Astra USA, 563 U.S. at 121-22 (amendment was Congressional effort to "strengthen and formalize HRSA's enforcement authority"). The repeated focus on diversion evinces a Congressional intent that (a)(5)(B) impose a real, substantive, non-token limit.

To the extent the legislative history of the 340B statute sheds any light on this question, it supports HRSA, not Genesis. Genesis critically misquotes, Pl. MSJ at 4, the 1992 House Report that is often cited for the proposition that the 340B Program was created so that covered entities could "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services," H.R. Rep. 102-384(II), at 12 (Sept. 22, 1992) (emphasis added to identify word omitted by Genesis). Using Genesis's own framing of the issue, *see* Pl. MSJ at 3, "eligible patients" is something less than all "patients," and thus Genesis's interpretation of (a)(5)(B) is wrong based on the House Report.

Turning to the specifics of Genesis's requested relief, it asks for a declaration that "[t]he plain wording of 42 U.S.C. § 256b(a)(5)(B) requires that any prescription from any source is available to a patient of a covered entity." Pl. MSJ at 20. At the outset, the intended meaning of the declaration is unclear. Obviously, an individual who is a patient of a covered entity can obtain a "prescription" somewhere else: no law prohibits an individual from seeking healthcare from multiple providers. The declaration is also circular: the core dispute here is the meaning of the phrase "patient of the entity" in (a)(5)(B) and yet the declaration uses those same terms ("available to a patient of a covered entity"). As it is worded, the declaration does not resolve the dispute and would simply add confusion about the meaning of (a)(5)(B).

Nevertheless, based on the arguments in Genesis's brief and the conduct discovered in the audit, Defendants see two ways to construe the intended meaning of the declaration. First, the "broader" possible meaning is that an individual can receive 340B-discount drugs from Genesis

regardless of the source of the individual's prescription. Understood this way, Genesis's proposed declaration is not limited to individuals who have received healthcare from Genesis (apart from receipt of the drug). As long as an individual has a prescription, she could fill her prescription with 340B drugs at Genesis—even if she has no other contact with Genesis before or after. Second, the "narrower" possible meaning is that an individual could receive 340B-discount drugs from Genesis regardless of the source of the individual's prescription, as long as Genesis has otherwise provided some sort of medical treatment to the individual at some point in the past. Whether it is construed broadly or narrowly, the above-mentioned declaration contravenes the 340B statute.

Genesis mainly rests on the dictionary definition of the word "patient" as "an individual awaiting or under medical care and treatment." Pl. MSJ at 16.[8] But that definition fails to give meaning to the phrase "of the entity" in (a)(5)(B). After all, the very act of providing a drug to an individual for medicinal purposes makes that individual the recipient of medical treatment—i.e., a "patient." Under Genesis's reasoning, the prohibition could simply read "a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient." Indeed, that would account for Genesis's position, *see* Pl. MSJ at 8, that the provision only prohibits non-treatment-related transfers of 340B drugs (i.e., "reselling" the drugs "in the open market"). But the statutory phrase "of the entity" must serve some purpose: "[a] statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant." *Hobbes v. Winn*, 524 U.S. 88, 101 (2004). Genesis's position thus flunks the "rule against superfluities," *id.*, and its cited authority actually supports Defendants' interpretation, Pl. MSJ at 7 n.2 (citing

[8] Genesis also provides links to various sub-regulatory documents issued by HRSA. *See* Pl. MSJ at 9, 11. Not all the links in Genesis's brief work. In any event, these manuals appear to pertain to HRSA's administration of Section 330 grants, 42 U.S.C. § 254b, which is an entirely separate program from the 340B Program, and they have no bearing on 340B Program requirements.

Bledsoe v. Cook, 70 F.4th 746, 750 (4th Cir. 2023), which rejected reading that would strip the statutory clause of "real-world purpose"). Genesis's understanding of the statute would allow it to essentially act as a pharmacy—one with a massive advantage, in that it has access to deeply discounted drugs. Pharmacies qua pharmacies[9] are not part of the 340B Program. *See* 42 U.S.C. § 256b(a)(4) (defining eligible healthcare providers). Thus, Genesis's proffered interpretation of (a)(5)(B) conflicts with (a)(4).

Even if Genesis clarifies that it seeks permission to provide 340B discount drugs to individuals to whom it has otherwise provided medical care in an "unrelated encounter," Pl. MSJ at 8, that interpretation of the statute fails for the same reasons. There is little practical distinction between Genesis's more ambitious statutory reading (it can provide 340B drugs to any individual, as long as it is not selling the drugs "for profit in the open market," Pl. MSJ at 8) and the fallback reading (it can provide 340B drugs to an individual who has had some sort of encounter with Genesis in the past, even if it is "unrelated" to the prescription in question, *id.*). The narrower position still allows Genesis to operate like a pharmacy: an individual who got a vaccine shot at Genesis five years ago becomes a "patient of" Genesis who could fill a prescription for oncology drugs today. These are not abstract hypotheticals: the administrative record shows that Genesis was classifying individuals as "340B eligible" based on an arbitrary two-year lookback period (which it could easily extend) and was providing 340B drugs to individuals for conditions different than what Genesis treated them for. *See supra* 7-9. Genesis's interpretation offers no statutory limit on how remote, in time or type of treatment, the "unrelated encounter" could be to the dispensing.

[9] Note the distinction from contract pharmacies, which are pharmacies that have arrangements with covered entities to receive and dispense drugs on behalf of those entities to the entities' patients, and which remit the reimbursement on those drugs to covered entities (minus any administrative fees or other costs that may exist in the contractual arrangement).

Thus, even the narrower reading of Genesis's proposed declaration puts (a)(5)(B) in conflict with (a)(4), which does not include pharmacies among its carefully circumscribed list of the types of healthcare providers entitled to participate in the Program. The Court must reject a reading that fails to interpret the "statute as a symmetrical and coherent regulatory scheme," fitting "all parts into an harmonious whole." *Alexander v. Carrington Mortg. Servs., LLC*, 23 F.4th 370, 378 (4th Cir. 2022) (quotes omitted). Genesis's position that the statute allows it to provide deeply discounted specialty drugs to a person to whom it once gave a flu shot cannot be squared with "common sense." *United States v. Jones*, 60 F.4th 230, 238 (4th Cir. 2023).

Genesis's approach also eviscerates other parts of the statute. Under the broader reading of the declaration, the numerous diversion-oversight provisions cited above, *see supra* 20-21 (citing section 256b(a)(5)(C), (a)(5)(D), (d)(2)(B)(v), (d)(3)(A), (d)(3)(B)(i)), would be "devoid of reason and effect" if a covered entity by definition met the requirements of (a)(5)(B) every time it dispensed drugs to an individual. *Great-West Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 218 (2002). And even the narrower reading—Genesis's "unrelated encounter" theory—enervates these oversight and compliance provisions. As explained above, HRSA cannot effectively conduct compliance audits of covered entities, satisfy its statutory mandate to prevent diversion, and ensure overall program integrity without a standard for gauging who qualifies as a patient of the entity. Requiring that an entity initiate a healthcare service that resulted in the prescription for a 340B drug, among other minimal standards, is wholly consistent with, if not compelled by the statutory scheme. Ultimately, to provide guidance to the regulated community, which can be sanctioned for "knowing and intentional" violations of (a)(5)(B), *see* § 256b(d)(2)(B)(v)(I)-(II), HRSA needs a barometer—apart from whichever policy or standard a particular covered entity among 13,000 happens to choose—for distinguishing compliant conduct from non-compliant conduct. HRSA's

commonsense interpretation of "patient of the entity" as applied to Genesis accomplishes exactly this goal without usurping legislative intent. Rather than harmonizing these compliance oversight and compliance provisions, Genesis's interpretation renders them ineffective when it comes to diversion.

Genesis's reading is also inconsistent with the practical realities of the healthcare system. Returning to the example above, say an individual who received oncology drugs dispensed by Genesis has an adverse reaction. Certainly, Genesis would not readily accept any sort of liability as that individual's medical provider just because it provided an unrelated vaccine to the individual five years ago. *Cf. In re Rezulin Prods. Liab. Litig.*, 133 F. Supp. 2d 272, 291 (S.D.N.Y. 2001) ("Patients who purchase prescription drugs from pharmacists do not negotiate or bargain with the pharmacists about the suitability of the product. … [T] he patient purchases the drug on the basis of discussions with his or her physician."). That highlights the fundamental problem with Genesis's position: when Genesis provides a 340B drug to the individual who had an "unrelated encounter" with Genesis, Genesis may not be generally responsible for that individual's medical care with respect to the drug—i.e., that individual is not a "patient of" Genesis qua medical provider (as opposed to Genesis qua pharmacy) for purposes of the drug. *Cf. Lansdell v. Am. Home Prods. Corp.*, No. 5:99-cv-02110-CLS, 1999 WL 33548541, at *5-*6 (N.D. Ala. Oct. 26, 1999) (explaining that the duties imposed upon pharmacists are narrow in order to avoid "wedg[ing] the pharmacist into the relationship between a physician and her or his patient"). So, too, the individual should not be considered a "patient of" Genesis for the purposes of the prohibition on diversion.

Genesis heavily relies on a decision related to a different aspect of the 340B Program, *Sanofi Aventis U.S. LLC v. H.H.S.*, 58 F.4th 696 (3d Cir. 2023). That case addressed covered

entities' use of contract pharmacies and manufacturers' obligations under section 256b(a)(1). It does not support Genesis's position on the scope of section 256b(a)(5)(B).

First, the *Sanofi* court framed the contract-pharmacy issue as one of HRSA attempting to fill a "statutory silence[]." 58 F. 4th at 699. Defendants disagree with that framing.[10] In any event, here Congress clearly has spoken on the issue: the whole point is that the parties are offering dueling interpretations of explicit statutory language that prohibits a covered entity from "reselling or otherwise transferring" 340B drugs to an individual who is not a "patient of the entity." And as discussed above, Congress has tasked the Secretary (and by delegation, HRSA) with effectuating the prohibition on diversion at multiple points in the statute.

Genesis's argument that Congress could have used different or additional language, *see* Pl. MSJ at 15, 17, 18, carries no weight. *See, e.g.*, *Caraco Pharma. Labs. v. Novo Nordisk A/S*, 566 U.S. 399, 416 (2012) ("[T[he mere possibility of clearer phrasing cannot defeat the most natural reading of a statute; if it could (with all due respect to Congress), we would interpret a great many statutes differently than we do."). And again, Genesis misapplies *Sanofi* when it argues that "Congress knew how to add [a prescription] restriction but did not." Pl. MSJ at 18. In rejecting HRSA's position concerning contract pharmacies, the *Sanofi* court noted that Congress had referred to delivery requirements and third-party entities acting on behalf of covered entities elsewhere in the statute and in a neighboring statute. 58 F.4th at 704. Genesis has identified no such analogous provisions, in the 340B statute or elsewhere, concerning patients or prescriptions to unlock this line of reasoning from the *Sanofi* court.

[10] Defendants disagree with the *Sanofi* court's interpretation of the 340B statute, and this Court is not bound by that decision. Defendants direct the Court to Defendants' briefs in that case to understand why the *Sanofi* court's analysis was incorrect and why HRSA's interpretation of the statute with respect to covered entities' use of contract pharmacies does not "fill in words that Congress left out." 58 F.4th at 699.

Notably, when Congress amended the 340B statute in 2010—an amendment that, as noted *supra* 20-21, specifically strengthened HRSA's oversight of covered entity compliance with the prohibition on diversion—Congress was presumably aware of HRSA's interpretation of the statute that a covered entity's mere dispensing of a drug to an individual did not make that individual a patient of the entity. 61 Fed. Reg. at 55,158. Congress declined to disturb HRSA's interpretation, thereby suggesting that HRSA's interpretation was consistent with Congressional intent. *See C.F.T.C. v. Schor*, 478 U.S. 833, 846 (1986). Genesis's argument about the 2010 amendments to the statute, Pl. MSJ at 17, has it backwards.

Genesis offers a one-sided characterization of the purpose of the 340B Program, implying that it exists for Genesis to maximize its revenues and dispense drugs to as many individuals as possible. *See* Pl. MSJ at 19-20. Genesis's reliance on *Sanofi* undercuts that view: the *Sanofi* court reasoned that the 340B Program does not exist for covered entities to "squeeze as much revenue out of it" as possible. 58 F.4th at 70. While Congress indeed wanted the 340B Program to help specific covered entities that serve vulnerable populations to better serve those populations, it is axiomatic that "no legislation pursues its purposes at all costs." *CTS Corp. v. Waldburger*, 573 U.S. 1, 12 (2014). Congress did not, for example, simply provide additional funding to covered entities directly, but developed a carefully calibrated drug-purchasing program with limitations—including the prohibition against diversion as well as other limitations. *See, e.g.*, § 256b(a)(5)(A) (prohibiting duplicate discounts), *id.* § 256b(a)(4)(L), (M) (certain covered entity hospitals cannot use group purchasing arrangements).

Genesis also takes an unduly narrow view of the purpose of (a)(5)(B), arguing that it exists solely to prohibit covered entities "from reselling the 340B drugs for profit in the open market." Pl. MSJ at 8. That ignores the actual text of the provision, which says a covered entity may not

"resell or otherwise transfer the drug to a person who is not a patient of the entity" (emphasis added). And ultimately, both the diversion provision itself and the statute as a whole evince a Congressional purpose to avoid what has happened here: Genesis using the 340B Program to generate large profits that make it an outlier among similarly-sized health centers. *See* A.R. 9183, 9351-52. Genesis admits that the prohibition on diversion exists "to prevent a covered entity from profiting from the [340B Program]," Pl. MSJ at 8, yet its conduct flouts that purpose.

And Genesis is wrong to try to compare its situation to that of the manufacturers in *Sanofi* who argued that HRSA's reading of section 256b gave rise to obligations that would (allegedly) conflict with their obligations under the Food, Drug, and Cosmetic Act. 58 F.4th at 705. Defendants disagree with the manufacturers' argument, but in any event the purported "legal bind" in that case was predicated on different statutory obligations. Genesis has identified no such obligations here.

Whatever the merit of Genesis's interpretation of the phrase "patient of the entity" "viewed in isolation," its interpretation is "untenable in light of the statute as a whole." *King v. Burwell*, 576 U.S. 473, 497 (2015) (alterations omitted). Only HRSA's reading takes proper account of the text of (a)(5)(B) in the context of the entire statutory scheme, including the delineation of covered entities in section 256b(a)(4) and the oversight and compliance provisions woven throughout the statute. Genesis's interpretation of (a)(5)(B) is incorrect, and Defendants are entitled to summary judgment.

B. Defendants agree that section 256b(a)(5)(B) refers only to a "patient of the entity" and that HRSA cannot interpret the 340B statute inconsistent with its text.

Genesis asks for a declaration that "[t]he only statutory requirement for 340B eligibility of a person is that the person be a patient of a covered entity, as clearly stated in [(a)(5)(B)]" and a

declaration that "interpretations or guidance of HRSA in contradiction of the plain wording of [(a)(5)(B)] are unlawful and unenforceable as a matter of law." Pl. MSJ at 20. There is no apparent dispute here. Defendants agree that the text of section 256b(a)(5)(B) says what it says: a covered entity may only "resell or otherwise transfer" 340B discount drugs to an individual that is a "patient of the entity."[11] Defendants also agree that HRSA cannot administer (a)(5)(B)—or any part of the 340B statute—contrary to the statute. While the parties may dispute the meaning of (a)(5)(B), it is axiomatic that agencies administering laws enacted by Congress must, indeed, abide by those laws. *See, e.g.*, *Brown & Williamson*, 529 U.S. at 125-26.

Because there is no dispute, there is no basis for declaratory relief. The Declaratory Judgment Act "confers a discretion on the courts rather than an absolute right upon the litigant." *Wilton v. Seven Falls Co.*, 515 U.S. 277, 287 (1995) (quotes omitted). Where the parties do not disagree, declaratory relief is improper in light of Article III's limits on federal-court jurisdiction as well as traditional principles of equity. *See White v. Nat'l Union Fire Ins. Co. of Pittsburgh*, 913 F.2d 165, 167-69 (4th Cir. 1990); *Pub. Serv. Comm'n of Utah v. Wycoff*, 344 U.S. 237, 243 (1952). Indeed, the Declaratory Judgment Act, 28 U.S.C. § 2201(a), allows for relief only where there is "actual controversy." *See Wycoff*, 344 U.S. at 243 ("The Federal Act omits status and limits the declaration to cases of actual controversy."). Entering these declarations serves no useful purpose; it simply raises the risk that some unanticipated ambiguity in the statements could cause problems in HRSA's administration of "public law" in future contexts that neither the Court nor the parties

[11] Defendants do not understand Genesis to be seeking a declaration about the scope of the statute as a whole, outside of section 256b(a)(5)(B). If that is what Genesis intends, it is obviously wrong on the face of the statute and it offers no argument about other statutory provisions. For example, section 256b(a)(5)(A) prohibits so-called "duplicate discounting"—obtaining a 340B discount and a Medicaid rebate on the same drug. In certain circumstances, that can result in a situation that could be characterized as "a person" not being "eligible" for 340B. The same is true if Genesis seeks a declaration with respect to all statutory requirements across the United States Code.

anticipate. *See id.* at 243-44. The Court should deny Genesis's request. *See also Stevens v. Osuna*, 877 F.3d 1293, 1311-13 (11th Cir. 2017) (affirming denial of declaratory relief based on, among other things, the lack of "necessity and usefulness of Plaintiff's requested declaration").

C. HRSA has authority to state its interpretation of section 256b(a)(5)(B).

Genesis also asks for a declaration that HRSA does not have "broad rulemaking authority" to "implement its interpretations and restrictions" to (a)(5)(B). Pl. MSJ at 21. The scope of this requested declaration is unclear. If it simply means that HRSA cannot administer the 340B Program contrary to the language of the 340B statute—including by "implementing" "restrictions" contrary to the "plain language" of the statute—Defendants do not disagree, as explained above. Once again, the lack of any actual dispute makes declaratory relief inappropriate.

But Defendants suspect that Genesis may want a declaration that HRSA cannot offer any interpretation of section 256b(a)(5)(B) because it lacks rulemaking authority. *See* Pl. MSJ at 10-11. If so, Genesis's argument conflates two distinct issues: (1) whether HRSA has been delegated rulemaking authority from Congress to issue binding rules that carry the force of law, versus (2) whether HRSA may issue statements setting forth its interpretation of the statutes it administers. Obviously, Genesis is not entitled to a declaratory order that would prevent HRSA from communicating its interpretation of (a)(5)(B) to stakeholders.

Genesis relies heavily on a 2014 decision that found that HHS could not promulgate a legislative regulation concerning the orphan-drug exclusion in 340B(e), 42 U.S.C. § 256b(e). *See* Pl. MSJ at 10-11 (citing *Pharma. Res. and Mfrs. of Am. v. H.H.S.*, 43 F. Supp. 3d 28 (D.D.C. 2014)). But legislative rulemaking is not at issue here, and Genesis ignores a 2015 decision from the same court that refutes its position in the instant case. *See Pharma. Res. and Mfrs. of Am. v. H.H.S.*, 138 F. Supp. 3d 31 (D.D.C. 2015) ("*PhRMA II*"). In *PhRMA II*, the court held that HHS had "authority to issue an Interpretive Rule prospectively setting forth the agency's reading of the

statute": "it is clear that HHS has the authority to advise the public of its interpretation of the statute." 138 F. Supp. 3d at 38-39 (emphasis omitted). *See also Mead Corp.*, 533 U.S. at 227 ("[W]hether or not they enjoy any express delegation of authority on a particular question, agencies charged with applying a statute necessarily make all sorts of interpretive choices."); *Gonzales v. Oregon*, 546 U.S. 243, 268-69 (2006).

In addition, both the administrative dispute resolution procedure mandated by the 340B statute, § 256b(d)(3)(A), and the Secretary's power to audit covered entity compliance and impose sanctions, *id.* (a)(5)(C), (a)(5)(D), (d)(2)(B)(v), cross-reference the prohibition on diversion. To carry out these provisions, "[q]uite obviously, then, . . . HHS will be required to interpret the reach of" (a)(5)(B). *PhRMA II*, 138 F. Supp. 3d at 39.

Moreover, Genesis is not bringing a pre-enforcement challenge to a broadly applicable interpretive statement; rather, it challenges HRSA's audit determination with respect to a single covered entity (Genesis). The agency action at issue stems from HRSA's oversight function, not any sort of prospective rulemaking function. And again, the statute plainly provides HRSA the authority to (1) audit covered entities for compliance with the statute's prohibition on diversion, § 256b(a)(5)(C); and (2) impose sanctions for non-compliance, *id.* (a)(5)(D), (d)(2)(B)(v). Obviously, that authority allows HRSA to explain to Genesis how HRSA interprets (a)(5)(B).

Ultimately, this declaration is too ambiguous and confusing to be entered as it stands. But no matter how one construes it, Defendants are entitled to summary judgment.

III. Declaratory Relief Must be Limited to Genesis.

Genesis appears to seek universal declarations about the scope of section 256b(a)(5)(B). But any remedy ordered by a federal court, including declaratory relief, must "be limited to the inadequacy that produced the injury in fact that the plaintiff has established." *Gill v. Whitford*, 138

S. Ct. 1916, 1931 (2018) (citation omitted). The Declaratory Judgment Act permits courts to "declare the rights and other legal relations of any interested party." 28 U.S.C. § 2201(a) (emphasis added). Declaratory relief is thus party-specific, *see Ogletree v. Cleveland State Univ.*, 2022 WL 17826730, at *11-*12 (N.D. Ohio Dec. 20, 2022) ("On its face" the Declaratory Judgment Act "limits the scope of a declaratory judgment to a party."), and nothing in the APA mandates a universal remedy, *see Va. Soc'y for Human Life, Inc. v. F.E.C.*, 263 F.3d 379, 393-94 (4th Cir. 2001). Unlike APA cases that seek to set aside a rulemaking, this case centers on a single audit determination directed to Genesis alone. In sum, Genesis is at most entitled to a declaration that only Genesis itself is not bound by the prescription-origin standard articulated in HRSA's March 2019 letter; moreover, any declaratory relief should be tied to the audit determination at issue. If the Court is inclined to rule for Genesis, it should allow Defendants to propose a properly limited judgment for the Court's consideration.

CONCLUSION

For the reasons set forth above, the Court should deny Genesis's motion for summary judgment; deny Genesis all its requested relief; and grant summary judgment to Defendants. If the Court is inclined to rule for Genesis, it should allow Defendants the opportunity to propose a judgment that addresses the problems of ambiguity and overbreadth discussed above.

Respectfully submitted,

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